



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

NOV 20 2007

Federal Advisory Committee Desk  
United States Acquisitions Section  
Anglo-American Acquisitions Division  
Library of Congress  
Washington, DC 20540-4174

Dear Sir or Madam,

Enclosed please find the Closed Meeting Reports of the Food and Drug Administration (FDA) for the fiscal year 2007.

These reports are submitted pursuant to Section 10(d) of the Federal Advisory Committee Act, which requires that an advisory committee holding a closed meeting issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

The Food and Drug Administration has 31 advisory committees. The FDA held 53 advisory committee meetings in FY2007. Of the 53 advisory committee meetings, 43 were fully open to the public and 10 were partially closed. FDA closes portions of the meetings to permit discussion of trade secrets and/or commercial or financial information obtained from a person and privileged or confidential (552b(c)(4)), or information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy (552b(c)(6)).

If you should need further information, please contact me 301-827-1220.

Sincerely,

Theresa L. Green  
Committee Management Officer  
Advisory Committee Oversight and  
Management Staff, FDA

Enclosures

## Advisory Committees of the Food and Drug Administration Closed Meetings in Fiscal Year 2007

### ***Center for Biologics Evaluation and Research:***

Cellular, Tissue and Gene Therapies Advisory Committee  
Vaccines and Related Biological Products Advisory Committee

### ***Center for Devices and Radiological Health***

Medical Devices Advisory Committee (consisting of reports for the following panels –  
Dental Products Panel and the Circulatory System Devices Panel)

### ***Center for Drug Evaluation and Research***

Antiviral Drugs, Advisory Committee



ANNUAL REPORT  
OF THE  
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE

For the period

October 1, 2006 through September 30, 2007

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met three times during the reporting period. The meetings were held in Bethesda, Md. and Gaithersburg, Md.

The dates of these meetings were: November 20, 2006, March 29-30, 2007, and July 26, 2007.

The meetings on November 20, 2006, March 29-30, 2007, and July 26, 2007 included a closed session to permit discussion of secret and confidential information or matters of a personal nature.

## ACCOMPLISHMENTS

November 20, 2006 meeting via teleconference. In open session, the Committee received information on the scope and mission of the research programs in the Laboratory of Immunobiology and Immunology, Office of Biotechnology Products, Center for Drug Evaluation and Research (CDER). The Committee held a closed session to discuss and make recommendations on issues related to the management and operation of the research program of the Office of Biotechnology Products, CDER. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations were utilized by FDA as part of its independent intramural program review.

March 29-30, 2007 meeting. In open session, the Committee discussed and made recommendations on issues related to Sipuleucel-T, sponsored by Dendreon Corp. for the treatment of men with asymptomatic metastatic hormone refractory prostate cancer. A BLA for Sipuleucel-T, Dendreon Corp., was reviewed by FDA and a complete response letter was issued to the sponsor. The Committee also discussed the Draft Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies. This guidance is being finalized by FDA. The Committee also received information on the scope and mission of the research programs in the division of Cellular and Gene Therapies, Center for Biologics Evaluation and Research. The Committee held a closed session to discuss and make recommendations on issues related to the management and operation of the research programs of the Cellular and Tissue Therapy Branch, and the Tumor Vaccines and Biotechnology Branch, Division of Cellular and Gene Therapies. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations were utilized by FDA as part of its independent intramural program review.

July 26, 2007 meeting via teleconference. In open session, the Committee received information on the scope and mission of: 1) the research programs in the Gene Transfer and Immunogenicity Branch, Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research (CBER), and 2) the Laboratory of Immunology and Laboratory Chemistry, Division of Therapeutic Proteins, and the Laboratory of Cell Biology, Division of Monoclonal Antibodies, both located in the Office of Biotechnology Products, Center for Drug Evaluation and Research (CDER). The Committee held a closed session to discuss and make recommendations on issues related to the management and operation of the research programs in the Divisions of Monoclonal Antibodies and Therapeutic Proteins, Office of Biotechnology Products, CDER and research programs of the Gene Transfer and Immunogenicity Branch, CBER. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations were utilized by FDA as part of its independent intramural program review.

Detailed information related to these meetings is available in the annual report.

10-23-2007  
Date

Gail Dapolito  
Gail Dapolito  
Executive Secretary

## **Cellular, Tissue and Gene Therapies Advisory Committee Committee Roster**

### **Chair**

#### **Walter John Urba, M.D., Ph.D.**

Expertise: Hematology / Oncology

Term: 09-29-2005 - 03-31-2009

Medical Director

Robert W. Franz Cancer Research Center

Earle A. Chiles Research Institute

Providence Portland Medical Center

4805 NE Glisan St, 5F-40

Portland, OR 97213

#### **James J. Mule, Ph.D.**

Expertise: Tumor Immunology/  
Immunotherapy

Term: 01-05-2004-03-31-2007

Associate Center Director

Translation Science and Technology  
Development

Michael McGillicuddy Endowed Chair

Melanoma Research and Treatment

H. Lee Moffitt Cancer Center and Research  
Institute

12902 Magnolia Drive, SRB-2

Tampa, FL 33612

### **Members**

#### **Matthew J. Allen, D.V.M., Ph.D.**

Expertise: Veterinary Medicine

Term: 05-25-2006 – 03-31-10

Associate Professor

Department of Orthopedic Surgery

SUNY Upstate Medical University

750 East Adams Street

Syracuse, NY 13210

#### **Michèle P. Calos, Ph.D.**

Expertise: Biochemistry/Molecular Biology

Term: 09-13-2004 - 03-31-2008

Associate Professor of Genetics

Department of Genetics, Rm. 334

Stanford University School of Medicine

300 Pasteur Drive

Stanford, California 94305-5120

### **Executive Secretary**

#### **Gail Dapolito**

Center for Biologics Evaluation and  
Research

Food and Drug Administration

1401 Rockville Pike

HFM-71

Rockville, MD 20852-1448

E-mail: [gail.dapolito@fda.hhs.gov](mailto:gail.dapolito@fda.hhs.gov)

Phone: 301-827-0314

Facsimile: 301-827-0294

#### **Richard J. Chappell, Ph.D.**

Expertise: Biostatistics and Medical Informatics

Term: 05-25-06 - 03-31-10

Professor

Department of Biostatistics and Medical

Informatics

The University of Wisconsin-Madison Medical  
School

600 Highland Avenue, KL6/430

Madison, Wisconsin 53792

**Jeffrey S. Chamberlain, Ph.D.**

Expertise: Genetics/Gene Therapy

Term: 09-29-2005 – 03-31-2009

Professor

Departments Neurology, Medicine and

Biochemistry

Health Sciences Center

University of Washington School of Medicine

1959 N.E. Pacific Street

Seattle, Washington 98195-7720

**Stanton L. Gerson, M.D.**

Expertise: Stem Cell Biology

Term: 05-25-06 - 03-31-10

Professor of Medicine, Oncology &

Environmental Health Sciences

Wearn Building Room 153

Case Western Reserve University

University Hospital of Cleveland

11100 Euclid Avenue

Cleveland, Ohio 44106-5065

**Farshid Guilak, Ph.D.**

Expertise: Biomedical Engineering

Term: 05-25-06 - 03-31-09

Laszlo Ormandy Professor of Orthopedic  
Surgery

Orthopedic Research Laboratories

Duke University Medical Center

MSRB Room 375, Box 3093

Durham, North Carolina 27710

**Kurt C. Gunter, M.D.\*\***

Expertise: Industry Representative

Term: 09-29-2005 - 03-31-2009

Medical Director, Cellular Therapy

Hospira, Inc.

Department 87W, Building H1

275 North Field Drive

Lake Forest, Illinois 60045

**Larry W. Kwak, M.D., Ph.D.**

Expertise: Tumor Immunology/Lymphoma

Term: 05-25-06 - 03-31-10

Chairman

Department of Lymphoma/Myeloma

University of Texas

M.D. Anderson Cancer Center

1515 Holcombe Boulevard – Unit 429

Houston, Texas 77030

**Doris A. Taylor, Ph.D.**

Expertise: Cardiovascular Cellular Therapy

Term: 05-25-06 - 03-31-10

Medtronic Bakken Professor

Center for Cardiovascular Repair

University of Minnesota

7-105A BSBE

312 Church Street SE

Minneapolis, Minnesota 55455

**Sharon F. Terry, M.D.\***

Expertise: Genetics / Consumer Representative

Term: 11-29-2004 - 03-31-2008

President and CEO

Genetic Alliance Organization

Suite 404

4301 Connecticut Ave, NW

Washington, DC 20008-2369

**William W. Tomford, Ph.D.**

Expertise: Orthopedic Surgery

Term: 09-13-2004 - 03-31-2008

Professor of Orthopedic Surgery

Massachusetts General Hospital

55 Fruit Street

Boston, MA 02114

**Savio Lau-Ching Woo, Ph.D.**

Expertise: Gene Therapy/Molecular Medicine

Term: 05-25-06 - 03-31-10

Professor of Gene and Cell Medicine

Mount Sinai School of Medicine

One Gustave L. Levy Place, Box 1496

New York, New York 10029

\*Consumer Representative

\*\*Industry Representative



ANNUAL REPORT  
OF THE  
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE  
For the period  
October 1, 2006 through September 30, 2007

FUNCTION

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met four times during the reporting period. Meetings were held in Bethesda, Maryland and Gaithersburg, Maryland.

The dates of those meetings were November 16, 2006, January 25, 2007, February 27-28, 2007, and May 16-17, 2007.

The meetings on November 16, 2006, January 25, 2007, and May 16-17, 2007 included closed sessions to permit discussion of secret or confidential commercial information or matters of a personal nature.

## ACCOMPLISHMENTS

November 16, 2006 meeting held via teleconference. The Committee received information on the scope and mission of the research programs in the Laboratory of Bacterial Toxins, Division of Bacterial Parasitic and Allergenic Products. The Committee also received information regarding the scope and mission of the research programs in the Laboratory of Vector Borne Virus Disease, the Laboratory of Hepatitis Viruses, and the Laboratory of Respiratory Viral Diseases, Division of Viral Products. The Committee held a closed session to discuss and make recommendations related to personnel and program actions for the intramural programs in the Laboratory of Bacterial Toxins, Division of Bacterial Parasitic and Allergenic Products and the Laboratory of Vector Borne Virus Disease, the Laboratory of Hepatitis Viruses, and the Laboratory of Respiratory Viral Diseases, Division of Viral Products. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

January 25, 2007 meeting. The Committee reviewed and made recommendations on the safety and immunogenicity of a DTaP-IPV-Hib vaccine, Pentacel, manufactured by Sanofi Pasteur Limited, for the protection of infants and young children against Diphtheria, Tetanus, Pertussis, and Hib. Pentacel was licensed by the FDA. In addition, the Committee received information on the scope and mission of the research programs in the Office of Vaccines Research and Review. The Committee held a closed session to discuss and make recommendations related to personnel and program actions for the intramural programs in the Office of Vaccines Research and Review. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations were utilized by FDA as part of its independent intramural program review.

February 27-28, 2007 meeting. The Committee reviewed, discussed and made recommendations in open session on the safety and immunogenicity of an H5N1 inactivated influenza vaccine sponsored by Sanofi Pasteur. This vaccine was licensed by the FDA. The Committee, in open session, discussed pandemic influenza vaccine strategies/clinical development of pandemic influenza vaccines. The FDA is continuing to plan for these emergency situations. In open session, the Committee also discussed and made recommendation on the strain selection for the Influenza Virus Vaccine for the 2007-2008 season. The Committee discussed influenza B strain including the history of B strain circulating lineages.

May 16-17, 2007 meeting. In open session, the Committee discussed and made recommendations on the safety and effectiveness of FluMist in a pediatric population less than 59 months of age sponsored by MedImmune. The FDA approved the license supplement for FluMist to include children between the ages of 2 and 5. The Committee, in open session, heard an overview of the Laboratory of Bacterial Polysaccharides and the Laboratory of Enteric and Sexually Transmitted Diseases, Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research Review and Review. The

Committee held a closed session to permit discussion of personnel and program actions for intramural programs in the Laboratory of Bacterial Polysaccharides and the Laboratory of Enteric and Sexually Transmitted Diseases. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review. In open session, the Committee discussed and made recommendations on the safety and effectiveness of ACAM2000 (live vaccinia virus smallpox vaccine) percutaneous scarification, manufactured by Acambis Inc. This vaccine is under review by the FDA.

Detailed information related to these meetings is available in the annual report.

Oct. 23, 2007  
Date

Christine A. Walsh  
Christine A. Walsh, RN  
Executive Secretary

## **Vaccines and Related Biological Products Advisory Committee Committee Roster**

### **Chair**

#### **Ruth A. Karron, M.D.**

Expertise: Pediatrics/Infectious Diseases  
Term: 02-01-2003 – 01-31-2008  
Professor  
Department of International Health  
Johns Hopkins School of Hygiene and  
Public Health  
624 N. Broadway  
Hampton House, Room 117  
Baltimore, MD 21205

#### **Monica M. Farley, M.D.**

Expertise: Bacterial Infectious Diseases  
Term: 02-01-2004 – 01-31-2008  
Professor of Medicine  
Department of Medicine  
Emory University School of Medicine  
VA Medical Center  
Research - Infectious Diseases (151)  
1670 Clairmont Road  
Atlanta, GA 30033

#### **Seth Hetherington, M.D.\*\***

Expertise: Industry Representative  
Term: 11-15-2005 – 09-30-2008  
Senior Vice President  
Clinical and Regulatory Affairs  
Icagen, Inc.  
4222 Emperor Boulevard, Suite 350  
Durham, North Carolina 27703

#### **Lisa Jackson, M.D., M.P.H.**

Expertise: Epidemiology & Infec. Dis.  
Term: 05-25-06 – 01-31-10  
Senior Scientific Investigator  
Group Health Cooperative  
1730 Minor Avenue, Suite 1600  
Seattle, Washington 98101

#### **Philip S. LaRussa, M.D.**

Expertise: Pediatrics / Virology  
Term: 02-01-2004 – 01-31-2008  
Professor of Clinical Pediatrics  
Columbia University, PH-4 West – 462  
622 West 168th Street  
New York, NY 10032

### **Executive Secretary**

#### **Christine A. Walsh, RN**

Center for Biologics Evaluation and  
Research  
Food and Drug Administration  
1401 Rockville Pike  
HFM-71  
Rockville, MD 20842-1448  
E-mail: Christine.Walsh@fda.hhs.gov  
Phone: 301-827-0314  
Facsimile: 301-827-0294

#### **John Modlin, M.D.**

Expertise: Pediatrics  
Term: 11-15-2005 – 01-31-2009  
Professor of Pediatrics  
Dartmouth-Hitchcock Medical Center  
Pediatric Administration  
One Medical Center Drive  
Lebanon, NH 03756

#### **Steven Self, Ph.D.**

Expertise: Biostatistics  
Term: 02-01-2004 – 01-31-2008  
Professor, Department of Biostatistics  
University of Washington  
Fred Hutchinson Cancer Research Center  
1100 Fairview Avenue, S., MS MW 500  
P.O. Box 19024  
Seattle, WA 98109

#### **Jack Stapleton, M.D.**

Expertise: Virology & Infec. Dis.  
Term: 05-25-2006 – 01-31-2010  
Professor and Director  
Division Director of Infectious Diseases  
Division of Internal Medicine, SW-54  
University of Iowa Hospital Clinic  
200 Hawkins Drive  
Iowa City, Iowa 52242

#### **Bonnie M. Word, M.D.**

Expertise: Pediatric Infectious Diseases  
Term: 02-01-2004 – 01-31-2008  
Assistant Professor of Pediatrics  
Baylor College of Medicine  
Texas Children's Hospital  
Clinical Care Center  
6621 Fannin Street, Suite 1740.01  
Houston, TX 77030

\*Consumer Representative

\*\*Industry Representative



ANNUAL REPORT

Food and Drug Administration  
Rockville MD 20857

OF THE

MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 2006 through September 30, 2007

FUNCTION

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The Panels engage in a number of activities to fulfill the functions the Federal Food, Drug and Cosmetic Act envisions for device advisory Panels. With the exception of the Medical Devices Dispute Resolution Panel, each Panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each Panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory Panel proceedings or Agency decisions or actions.

## MEETINGS

The Medical Devices Advisory Committee held 14 meetings during the reporting period in Gaithersburg, Maryland.

Below are the dates of all device panel meetings held during FY 2007 (10/1/06 to 9/30/07) and **UNDERLINED** dates represent meetings that had closed sessions:

<b><u>11/9/06</u></b>	Dental Products Panel
11/16/06	Immunology Devices Panel
12/6/06	Clinical Chemistry and Clinical Toxicology Devices Panel
12/7-8/06	Circulatory System Devices Panel
12/15/06	Medical Devices Dispute Resolution Panel
1/26/07	Neurological Devices Panel
2/22/07	Orthopaedic and Rehabilitation Devices Panel
<b><u>3/1-2/07</u></b>	Circulatory System Devices Panel
4/19/07	Medical Devices Dispute Resolution Panel
4/24/07	Orthopaedic and Rehabilitation Devices Panel
5/4/07	General Hospital and Personal Use Devices Panel
6/27/07	Circulatory System Devices Panel
7/17/07	Orthopaedic and Rehabilitation Devices Panel
9/19-20/07	Circulatory System Devices Panel

## DENTAL PRODUCTS PANEL

### MEMBERSHIP

A roster of members is attached.

### MEETINGS

The committee met once during the reporting period in Gaithersburg, MD.

The date of the meeting was November 9, 2006.

The meeting on November 9, 2006 included a closed session to permit presentation or discussion of trade secret and/or confidential commercial information.

### ACCOMPLISHMENTS

#### **At the November 9, 2006 meeting:**


The Panel met and voted on a PMA for "InFuse Bone Graft" from Medtronic Sofamor Danek. The device is made from collagen material, contains a bone morphogenetic protein, and is indicated as an alternative to autogenous bone graft for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets. The Panel voted 6-0 for "approvable with conditions." The condition included that the labeling should note that in regards to the ridge augmentation at tooth extraction sites, this device has not been tested in the molar region of the mouth, or in the mandible. The Panel imposed this condition because it believed that it was not clear that the data presented – from the anterior region of the maxilla – demonstrated effectiveness of this device for ridge augmentation at tooth extraction sites throughout the entire mouth.

On March 9, 2007, the PMA for Medtronic's InFuse Bone Graft was approved by FDA.

***Closed Committee Deliberations:*** On November 9, 2006 there was a closed session to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future agency issues (5 U.S.C.552b(c)(4)).

September 30, 2007

Date

  
Michael J. Ryan  
Executive Secretary

## **Dental Products Panel of the Medical Devices Advisory Committee Roster**

### ***Chairperson***

**Richard G. Burton, D.D.S., M.S.**

Expertise: Oral Surgery  
Term: 5/4/06 - 10/31/09  
Professor and Vice Chairman  
Div. of Oral and Maxillofacial Surgery  
Hospital Dentistry Institute  
University of Iowa Hospitals and Clinics  
200 Hawkins Drive, 51300PPF  
Iowa City, IA 52242-1009

### ***Executive Secretary***

**Michael J. Ryan**

Center for Devices and Radiological Health  
Office of Device Evaluation/DAGID/DDB  
9200 Corporate Blvd. HFZ-480  
Rockville, MD 20850  
240-276-3773  
240-276-3789

**Man Wai Ng, D.D.S., M.P.H.**

Expertise: Pediatric Dentistry; Dental Health,  
Clinical  
Term: 3/22/04 - 10/31/06  
Chief, Department of Dentistry  
Department of Dentistry  
Children's Hospital Boston  
300 Longwood Ave.  
Boston, MA 02115

**John R. Zuniga, Ph.D., D.M.D.**

Expertise: Oral Surgery; Neurosciences  
Term: 3/22/04 - 10/31/06  
Professor and Chairman, Dept. of Surgery  
Div., Oral and Maxillofacial Surgery  
University of Texas, Southwestern Medical Ctr.  
5323 Harry Hines Blvd.  
Dallas, TX 75390-9109

**Salomon Amar, D.D.S., Ph.D.**

Expertise: Periodontics; Dental Sciences, Clinical  
Term: 3/22/04 - 10/31/07  
Professor  
Dept. of Periodontology and Oral Biology  
Boston University  
700 Albany Street, W201E  
Boston, MA 02118

**Yiming Li Ph.D., D.D.S.**

Expertise: Toxicology  
Term: 5/4/06 - 10/31/09  
Professor and Director  
Center for Dental Research  
Loma Linda University School of Dentistry  
24876 Taylor Street, Room 112  
Loma Linda, CA 92350

**\*\* Mason Diamond, DDS**

Expertise: Pain Management; Clinical Trial  
Research  
Term: 5/4/06 - 10/31/09  
Vice President, Clinical and Regulatory Affairs  
TyRx Pharma, Inc.  
1 Deer Park Drive, Suite G  
Monmouth Junction, NJ 08852

**William J. O'Brien, M.S., Ph.D.**

Expertise: Material Sciences  
Term: 3/22/04 - 10/31/07  
Professor of Dentistry  
Dept. of Biologic and Materials Science  
Univ. of Michigan School of Dentistry  
1011 N. University, Room 2203  
Ann Arbor, MI 48103

**\* Michael D. Fleming, D.D.S.**

Expertise: Dental Sciences, Clinical  
Term: 6/27/06 - 10/31/09  
Dentist  
1858 Hillandale Rd. Suite 200  
Durham, NC 27705

**Domenick T. Zero, D.D.S., M.S.**

Expertise: Cardiology; Dental Sciences, Clinical  
Term: 3/22/04 - 10/31/07  
Professor and Chairman  
Preventive and Community Dentistry  
Indiana Univ. School of Dentistry  
415 Lansing Street  
Indianapolis, IN 46202-2876

**\*Consumer Representative**

**\*\*Industry Representative**

## CIRCULATORY SYSTEM DEVICES PANEL

### MEMBERSHIP

A roster of members is attached.

### MEETINGS

The committee met four times during the reporting period in Gaithersburg, MD.

The dates of the meetings were December 7-8, 2006; March 1-2, 2007; June 27, 2007; and September 19-20, 2007.

The meeting on March 2, 2007 included a closed session to permit presentation or discussion of trade secret and/or confidential commercial information.

### ACCOMPLISHMENTS

#### **At the December 7-8, 2006 meeting:**

The Panel discussed and made recommendations regarding issues related to stent thrombosis in coronary drug-eluting stents (DES). The purpose of the meeting was: (1) to provide a forum for the presentation of clinical data relevant to the issue of DES thrombosis (both when DES are used according to their labeled indication and in more complex patients beyond their labeled indication) and (2) to address the appropriate duration of clopidogrel use in DES patients. A major accomplishment of the meeting was the Panel agreed that insufficient available data precluded an opinion regarding whether concerns related to off-label use were similar between the currently approved DES.

#### **At the March 1-2, 2007 meeting:**

On the first day of a 2-day meeting in March 2007, the Panel discussed, made recommendations and voted on the premarket approval application (PMA), sponsored by Medtronic Inc., for the Chronicle Implantable Hemodynamic Monitoring System. This implantable device is intended to reduce hospitalization events or equivalent events for worsening heart failure in patients with moderate to advanced heart failure. The Panel voted 9-2 in favor of "not-approvable." The Panel cited concerns regarding lack of clinical effectiveness as the main reason for their recommendation.

On the second day of the meeting, the Panel discussed and made recommendations regarding clinical trial designs for Patent Foramen Ovale (PFO) closure devices intended to prevent recurrent stroke. The Panel was in general agreement that Randomized Controlled Trials (RCTs) were needed to ensure the appropriateness of the rationale of using PFO closure devices to prevent recurrent stroke.

**Closed Committee Deliberations:** On March 2, 2007 there was a closed session to permit the discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) presented by sponsors.

**At the June 27, 2007 meeting:**

The Panel discussed, made recommendations, and voted on a PMA, sponsored by CryoCor Inc., for the CryoCor Cryoablation System, intended for the treatment of isthmus-dependent atrial flutter in patients 18 years or older. The Panel voted 8-2 in favor of "approvable with conditions." Among the conditions of approval were:

- A post-market study with specific endpoints recommended during the Panel discussion.
- An on-site physician training program.
- Labeling modifications that were summarized during the Panel discussion.

Decision: On August 1, 2007, the PMA for CryoCor Inc.'s CryoCor Cryoablation System was approved by FDA.

**At the September 19-20, 2007 meeting:**

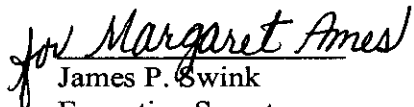
The Panel discussed, made recommendations and voted on a PMA, sponsored by SyntheMed, Inc., for the REPEL-CV. It is a surgical adjuvant indicated for reducing the incidence, severity and extent of post-operative adhesion formation in patients undergoing cardiac surgery. The Panel voted 8-3 in favor of SyntheMed Inc.'s Repel as "approvable with conditions." The recommended conditions of approval were summarized as follows:

- Removal of the contraindication that prevents use of the device in patients with left ventricular assist devices.
- Modification of the indications statement to remove "incidence and extent."
- Modification of the indications statement to limit use of the device to a pediatric population as defined by FDA.
- Modification of the indications statement to specify that patients receiving the device would have a high likelihood of a reoperation.
- Development of a post-approval study to evaluate long-term safety and effectiveness.

On the second day of the September meeting, the Panel discussed and made recommendations regarding clinical trial designs for cardiac ablation devices designed to treat patients with medically refractory atrial fibrillation (AF). The Panel was in general agreement that Randomized Controlled Trials (RCT's) would provide the best evidence to support a PMA for an ablation device intended to treat medically refractory AF. The Panel discussed viable alternative trial designs, endpoints and barriers to enrollment.

September 30, 2007

Date

  
James P. Swink  
Executive Secretary

## Circulatory System Devices Panel of the Medical Devices Advisory Committee Roster

### **Chairman**

**William H. Maisel, M.D., M.P.H.**

Expertise: Cardiology

Term: 1/31/05 – 6/30/07

Assistant Professor of Medicine

Cardiovascular Division

Beth Israel Deaconess Medical Center

185 Pilgrim Road, Baker 4

Boston, MA 02215

### **Executive Secretary**

**James Swink**

Office of Device Evaluation/DCD

9200 Corporate Blvd.

HFZ-450

Rockville, MD 20850

240-276-4000

240-276-4181

**Mitchell W. Krucoff, M.D.**

Expertise: Cardiology; Cardiovascular Disease & Physiology

Term: 11/17/03 – 6/30/07

Associate Professor of Medicine

Dept. of Medicine/Cardiology

Duke Univ. Medical Center

508 Fulton Street

Durham, NC 27705

**Christopher J. White, M.D.**

Expertise: Cardiology

Term: 11/17/05 – 6/30/07

Chairman, Department of Cardiology

Ochsner Clinic

1514 Jefferson Highway

New Orleans, LA 70121

**\* Linda A. Mottle, M.S.M., R.N., CCRP**

Expertise: Clinical Research Manager; ICU Nurse

Term: 7/14/04 - 6/30/08

Associate Clinical Professor and

Dir., Clinical Trials Research Mgt. Program

Arizona State University

College of Nursing and Healthcare Innovation

500 N. 3rd Street Room #466 MC3020

Phoenix, AZ 85004

**Clyde W. Yancy, M.D.**

Expertise: Heart Failure; Cardiac Transplant

Term: 1/31/05 - 6/30/08

Medical Director

Baylor Heart and Vascular Institute

Baylor University Medical Center

3500 Gaston Ave., Suite H-030

Dallas, TX 75246

**Richard L. Page, M.D.**

Expertise: Clinical Cardiac Electrophysiology; Pharmacology

Term: 1/31/05 - 6/30/08

Professor of Medicine

Head, Div. of Cardiology

Univ. of Washington School of Medicine AA510

HSC

1959 NE Pacific Street

Box 356422

Seattle, WA 98195-6422

**\*\* Marcia S. Yaross, Ph.D.**

Expertise: Electrophysiology Devices; Clinical Research

Term: 7/1/05 - 6/30/09

VP, Clinical, Quality and Regulatory Affairs

Biosense Webster, Inc. (a J&J Company)

3333 Diamond Canyon Road

Diamond Bar, CA 91765

**John C. Somberg, M.D.**

Expertise: Cardiovascular Pharmacology

Term: 1/30/05 - 6/30/08

Chief, Division of Clinical Pharmacology

Professor of Medicine and Pharmacology

Rush Univ. Medical Center

21 N. Skokie Valley Highway

Suite G-3

Lake Bluff, IL 60044

**Sharon-Lise T. Normand, Ph.D.:** Expertise:

Statistics, Health Policy

Term: 11/17/03 - 6/30/07

Professor of Health Care Policy (Biostatistics)

Harvard Medical School

180 Longwood Ave.

Boston, MA 02115-5899

\*Consumer Representative

\*\*Industry Representative



ANNUAL REPORT OF THE

Food and Drug Administration  
Rockville MD 20857

Antiviral Drugs Advisory Committee

for the period October 1, 2006 through September 30, 2007

• FUNCTION

The Antiviral Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

MEMBERSHIP

See attached Roster

MEETINGS

The committee met 3 times during the reporting period in Silver Spring, Maryland.

The dates of the meetings were: October 19-20, 2006, April 24, 2007, and September 5-6, 2007.

The meetings on October 19-20, 2006 and September 5-6, 2007 included a closed session to permit discussion, presentation, and review of trade secret and/or confidential commercial information or disclosure would constitute a clearly unwarranted invasion of personal.

ACCOMPLISHMENTS

The activities of the committee during this meeting included:

On October 19 -20, 2006, the committee discussed clinical trial design issues in the development of products for treatment of chronic hepatitis C infection. The meeting was convened in response to the growing number of products in development for this indication. The primary objectives for committee deliberations were to discuss issues relating to the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up. October 20, 2006 the meeting was open to the public from 8 a.m. to 12 noon. During the open session, the committee provided consensus recommendations to the FDA without taking a vote. The committee recommended specific patient populations to receive drug therapy during the initial time of approval of products to treat hepatitis c infection based on stage of disease, treatment experience, genotype, co-morbidities, pre and post liver transplantation, pediatrics, and racial ethnic groups. The committee established uniform trial design definitions including null, partial,

and responder-relapsers which represent a unique class needing to be separated, yet included in clinical trials. The committee also made suggestions on control selections for clinical trials including treatment-naïve versus treatment-experienced patients as well as compensated and decompensated liver disease. The committee also made recommendations on study-design evaluation of efficacy including primary endpoints to be used in clinical trials and timing of assessing primary endpoints. The committee also recommended adding an investigational agent to the standard-of-care and agreed that superiority should be demonstrated for the investigational agent while non-inferiority trials should be planned to follow superiority studies. The committee also agreed that ribavirin should not be substituted in clinical trials and expressed concern over monotherapy due to potential of resistance. Finally, the committee agreed that long-term follow-up is beneficial in hepatitis c clinical trials.

On October 20, 2006, from 1p.m - 4p.m., the committee met in closed session to permit discussion and review of trade secret and/or confidential information and to receive a committee update on activities and decisions of the review division.

On April 24, 2007, the committee discussed new drug application (NDA) 022-128, maraviroc 300 milligram tablets, Pfizer, Inc., proposed for the treatment of antiretroviral-experienced patients with chemokine (c-c motif) receptor 5 (CCR5)--tropic human immunodeficiency virus (HIV). The committee recommended 12-0 that safety and efficacy data presented support accelerated approval of maraviroc for treatment-experienced HIV-1 infected patients with CCR5-tropic virus. The committee also recommended 12-0 that data support the Applicant's proposed dosing. The committee agreed that tropism testing is necessary to select patients for treatment with maraviroc and recommended testing at the time of virologic failure. On August 6, 2007, Selzentry (maraviroc) was granted accelerated approval by the FDA for combination antiretroviral treatment of adults infected only with detectable CCR5-tropic HIV-1, who have evidence of viral replication and who have HIV-1 strains resistant to multiple antiretroviral agents. The Trofile assay designed to identify candidates for treatment with maraviroc will be introduced in tandem.


On September 5-6, 2007, the committee discussed new drug application (NDA) 22-145, raltegravir potassium, integrase inhibitor 400 milligram tablets, Merck & Co., Inc., for the treatment of Human Immunodeficiency Virus-1 (HIV-1) infection in combination with other antiretroviral agents in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. The committee recommended 11-0 that data support accelerated approval of raltegravir for treatment of HIV-1 infection in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. The committee suggested that post-marketing commitments include studies to capture historically relevant patient populations and agreed that a period of not less than five years is appropriate duration for an active surveillance program. The committee also made suggestion on strategies to increase study enrollment of women and minorities including a longer enrollment time period built into the study

design as well as dictating more specific enrollment standards by demonstrating efforts to capture historically relevant patient populations.

On September 6, 2007, the committee discussed and reviewed a phase 3 protocol in the development of a new indication.

The meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552(c) (4)).

10/22/07  
Date

  
\_\_\_\_\_  
Cicely Reese, Pharm.D.  
Designated Federal Officer

## **Antiviral Drugs Advisory Committee Roster**

### **CHAIR**

**Richard H. Haubrich, M.D.**

Expertise: Infectious Diseases

Term: 11/1/2003-10/31/2007

Associate Professor of Medicine

University of California, San Diego

Antiviral Research Center

150 West Washington Street, Suite 100

San Diego, California 92103

**Barbara D. Alexander, M.D.**

Expertise: Infectious Diseases

Term: 6/15/2007 – 10/31/2010

Assistant Professor

Division of Infectious Diseases

and International Health

Research Drive

Duke University Medical Center

Durham, North Carolina 27707

**Janet W. Andersen, Sc.D.**

Expertise: Biostatistics in AIDS Research

Term: 01/16/2006– 10/31/2009

Executive Director

Center for Biostatistics & AIDS Research

Harvard University School of Public Health

651 Huntington Avenue, FXB – 621

Boston, Massachusetts 02115

**John A. Bartlett, M.D.**

Expertise: Infectious Diseases

Term: 7/8/03 - 10/31/06

Professor of Medicine

Division of Infectious Diseases

Duke University Medical Center

P.O. Box 3238

Durham, North Carolina 27705

**Gail J. Demmler, M.D.**

Expertise: Respiratory Viruses and Pediatrics

Term: 3/31/2006 – 10/31/2009

Professor of Pediatrics

Department of Pediatrics and Pathology

Baylor College of Medicine

One Baylor Plaza

Houston, Texas 77030

### **DESIGNATED FEDERAL OFFICER**

**Cicely Reese, Pharm.D.**

Advisors and Consultants Staff

Center for Drug Evaluation and Research

Food and Drug Administration, HFD-021

5630 Fishers Lane, Room 1099

Rockville, Maryland 20857

**Robert M. Grant, M.D.**

Expertise: HIV, Pulmonary and Critical Care

Term: 6/15/2007 – 10/31/2009

Associate Investigator

J. David Gladstone Institute of Virology and

Immunology

University of California, San Francisco

1650 Owens Street

San Francisco, California 94158

**Peter L. Havens, M.D.**

Expertise: Pediatric Infectious Diseases

Term: 1/16/2006 – 10/31/2009

Professor of Pediatrics

Medical College of Wisconsin

Department of Pediatrics – MFRG

Milwaukee, WI 53226

**Craig W. Hendrix, M.D.**

Expertise: Clinical Pharmacology

Term: 6/15/2007 – 10/31/2010

Associate Professor

Division of Clinical Pharmacology

The Johns Hopkins University

School of Medicine

600 North Wolf Street

Baltimore, Maryland 21287

**Victoria A. Johnson, M.D.**

Expertise: Infectious Diseases

Term: 12/16/02 – 10/31/06

Professor of Medicine and Microbiology

University of Alabama at Birmingham

School of Medicine

Division of Infectious Diseases

THT 229, 1530 3<sup>rd</sup> Avenue South

Birmingham, Alabama 35294

**Douglas G. Fish, M.D.**  
Expertise: Infectious Diseases  
Term: 7/8/03 – 10/31/06  
Division Head, Division of HIV Medicine  
Assistant Professor of Medicine  
Albany Medical College  
47 New Scotland Avenue, Mail Code: 158  
Albany, New York 12208

**Marshall J. Glesby, M.D., Ph.D.**  
Expertise: Infectious Diseases  
Term: 6/15/2007 – 10/31/2009  
Associate Professor  
Weill Medical College of Cornell University  
525 East 68<sup>th</sup> Street  
New York, New York 10021

**Amneris E. Luque, M.D.**  
Expertise: Infectious Diseases  
Term: 6/15/2007 – 10/31/2010  
Associate Professor of Medicine  
Infectious Diseases/Division/Department  
of Medicine  
610 Elmwood Avenue  
Strong Memorial Hospital  
Rochester, New York 14642

**Ian M. McGowan, M.D., Ph.D.,**  
Expertise: HIV Medicine/Gastroenterology  
Term: 6/15/2007 -10/31/2010  
Visiting Professor of Medicine  
University of Pittsburgh Medical School  
Magee Women's Research Institute  
204 Craft Avenue  
Room B505  
Pittsburgh, Pennsylvania 15213

**\*Robert J. Munk, Ph.D.**  
Expertise: HIV/AIDS  
Term: 3/14/2004 – 10/31/2007  
Coordinator, New Mexico AIDS Info Net  
34A Puma Way  
P.O. Box 810  
Arroyo Seco, New Mexico 87514

**Lynn A. Paxton, M.D., M.P.H.**  
Expertise: Internal Medicine  
Term: 11/1/2003 – 10/31/2007  
Chief, Sexual Transmission and  
Injection Drug Use Studies Section  
Centers for Disease Control and Prevention  
1600 Clifton Road, MS-E45  
Atlanta, Georgia 30333

**Maribel Rodríguez-Torres, M.D.**  
Expertise: Viral Hepatitis and Gastroenterology  
Term: 12/27/2004 – 10/31/2008  
Physician, Fundacion de Investigacion de Diego,  
#359, Suite 302  
Santurce, Puerto Rico 00909

**Kenneth E. Sherman, M.D., Ph.D.**  
Expertise: Hepatology  
Term: 12/16/02 – 10/31/06  
Director  
Hepatology and Liver Transplant Medicine Section  
University of Cincinnati College of Medicine  
231 Albert B. Sabin Way  
Medical Science Building, Room ML 0595  
Cincinnati, Ohio 45267

**\*\*Eugene Sun, M.D.**  
Expertise: Infectious Diseases  
Term: 2/2/2004 – 10/31/2007  
Divisional Vice President  
Global Pharmaceutical Development  
Global Pharmaceutical Research and Development,  
Abbott Laboratories  
200 Abbott Park Road  
Department R435, Building LFCP4-4  
Abbott Park, Illinois 60064

\* Consumer Representative  
\*\* Industry Representative